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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/812,351	03/29/2004	Gary Durack	MTC 2001.1 (37-21(53260)B	2698
321	7590	06/15/2007	EXAMINER	
SENNIGER POWERS ONE METROPOLITAN SQUARE 16TH FLOOR ST LOUIS, MO 63102			WALLENHORST, MAUREEN	
			ART UNIT	PAPER NUMBER
			1743	
			NOTIFICATION DATE	DELIVERY MODE
			06/15/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspatents@senniger.com

Office Action Summary

Application No.

10/812,351

Applicant(s)

DURACK ET AL.

Examiner

Maureen M. Wallenhorst

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 45-64 and 81 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 45, 47-49, 53-59, 62-64 and 81 is/are rejected.
- 7) ☒ Claim(s) 46, 50-52, 60 and 61 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

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1. Applicants are informed that the instant application has been transferred to Examiner Maureen Wallenhorst.
2. Applicant's election without traverse of Group III, claims 45-64, in the reply filed on April 5, 2007 is acknowledged.
3. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

4. The abstract of the disclosure is objected to because of the inclusion of legal phraseology such as "comprises" and "comprising". Correction is required. See MPEP § 608.01(b).
5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 45, 47-49, 54-55, 57, 59, 63-64 and 81 are rejected under 35 U.S.C. 102(b) as being anticipated by Hoffman et al (WO 01/29538).

Hoffman et al teach of a flow cytometer apparatus and a method for examining particles such as blood or sperm cells using the apparatus. The apparatus 100 comprises a flow cell 104 in which a sheath fluid surrounds a cell stream, and the combined sheath fluid and cell stream exits the flow cell 104 via an opening in a capillary 109 as a sample stream 110. The sample stream

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remains intact until breaking off into droplets at the droplet break off point 112. The distance from the opening in the capillary 109 at which the droplet break off point 112 occurs, and the frequency or rate at which the droplets are formed are governed by the fluid pressure, as well as the amplitude and frequency of oscillation of an oscillating device 114. The oscillating device 114 is connected to an alternating voltage source 116 whose output voltage amplitude, frequency and phase is controlled by a controller 118 which can be a microprocessor or other controlling device. The amplitude of the alternating voltage signal output by alternating voltage source 116 can be increased or decreased by controller 118 to increase or decrease the distance from opening 110 at which the droplet break off point 112 occurs. Also, the frequency of the alternating voltage signal output by alternating voltage source 116 can be increased or decreased by controller 118 to increase or decrease the rate at which droplets of sample fluid are formed at the droplet break off point 112. The flow cytometer apparatus 100 comprises a plurality of flow cytometry units in the form of a plurality of cell evaluation assemblies 120. Each cell evaluation assembly comprises a laser 122, an LED assembly 124 having a lens 126, an optional filter 128, a first and second dichroic mirror 130, 132, a first detector 134 having filter 136, and a second detector 138 having a filter 140. The laser 122 can be any type of known laser such as a diode laser, semiconductor laser, etc, which is controlled by the controller 118 to emit laser light which radiates onto the flow stream 110. The detectors 134, 138 can each be photomultiplier tubes or any other suitable type of light detecting device. The detectors 134 and 138 are positioned within the path of light exiting from the immersion lens arrangement 111 so that the lens arrangement can focus an image of the sample stream 110 onto the filters 136, 140. The filters permit fluorescent light from the cells, which have been excited by light from LED assembly

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124, to pass detector 134, and filter 140 permits fluorescent light emitted from the cells which have been excited by light from laser 122 to pass to detector 138. The light emitted by the laser 124 radiates onto the flow stream 110 at a point which is about 100 microns upstream of the point at which the light emitted by LED 125 radiates onto flow stream 110. The flow cytometry units 120 can include any number of lasers, dichroic mirrors, detectors and LED assemblies, which can be arranged to evaluate different types of particles and different characteristics of the cells, such as size, complexity and granularity. In addition, although Figure 1 in Hoffman et al only depicts a single flow cytometry unit 120, the flow cytometry apparatus 100 can employ any number of flow cytometry units or cell evaluation assemblies 120 having one or more lasers, one or more LED assemblies, one or more mirrors and one or more detectors. The controller 118 receives time-varying signals from each of the flow cytometry units 120 in a continuous manner, and processes the signals in order to analyze and sort the blood or sperm cells. The controller 118 also serves to control the lasers 122, detectors 134 and 138, and the LED assemblies. The detectors 126 and 128 each convert the light they receive into electrical signals, which are interpreted by controller 118 as representing a characteristic of the cells in the sample fluid at a given sampling time. The controller 118 can also control a charging unit 184 to charge cells of interest in accordance with their detected characteristic, so that the cells can be sorted by deflection plates 186 and 188, which serve to sort cells of interest into different collection vessels 190, 192 and 194. The cells in the sample reservoir 106 are treated with a stain prior to sorting in the apparatus so that the cells fluoresce when irradiated with light of a certain wavelength. Hoffman et al also teach that the lasers and LED assemblies in the flow cytometry units 120 can utilize an epi-illumination configuration. See Figures 1-2 and pages 8-12, 14 and example 1 on

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page 21 of Hoffman et al. Since the instant claims are interpreted as broadly as possible, each of the cell evaluation assemblies 120 in the flow cytometer apparatus taught by Hoffman et al are considered a “plurality of flow cytometry units”, as recited in the instant claims.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 53, 56, 58 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoffman et al. For a teaching of Hoffman et al, see previous paragraphs in this Office action.

Hoffman et al fail to teach that the plurality of cell evaluation assemblies or flow cytometry units 120 are interchangeable modules in the common housing of the flow cytometer apparatus, and fail to teach that the processor is operable to output the rate at which particles are separated in the apparatus, the decision boundary used by each unit to discriminate between particles, and the operation of one unit in relation to another unit. However, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to render each of the flow cytometry units 120 taught by Hoffman et al as an interchangeable module in the common

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housing of the apparatus so as to allow one of the units to be replaced when it is not working properly without having to replace or shut down the entire cytometer apparatus, thus allowing a more efficient operation of the device. It also would have been obvious to one of ordinary skill in the art to operate the processor to output the rate at which particles are separated in the apparatus, the decision boundary used by each unit to discriminate between particles, and the operation of one unit in relation to another unit since these are common control parameters in a flow cytometer controlled by a processor such as a computer that provide an indication to an operator of the cytometer as to whether it is operating properly to sort particles and the criteria used to sort the particles.

10. Claims 46, 50-52 and 60-61 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims since none of the prior art of record teaches or fairly suggests a multi-channel particle sorting apparatus comprising a plurality of flow cytometry units, wherein each separate unit comprises its own cell stream where the cells are individually sorted using a jet-in-air droplet technique, and wherein a common source of electromagnetic radiation is used for exciting fluorescently-labeled cells in each of the separate cell streams in each of the separate sorting units.

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Please make note of: Evans et al (US 2007/0117086), who teaches of an apparatus with multiple flow cytometry units substantially the same as recited in the instant claims. However, the effective filing date of the application upon which this publication is based is after the

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effective filing date of the instant application. Also, please make note of: Johnson et al (article), Fritz, Johnson, Kurabayashi et al, Martin et al and Van den Engh et al who all teach of flow cytometer devices having multiple light sources and detectors therein.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Thursday from 6:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

June 4, 2007

Maureen M. Wallenhorst
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PRIMARY EXAMINER
GROUP 1700